

Application No. 10/005,438
Attorney Docket: TNX95-02ABB
Customer Number: 26839

diseases, including hepatitis B. IFN- β has been approved for use in treatment of multiple sclerosis. Thus, these cytokines have already shown to have some biological stability and half-life in the body and clearly reach the intended target. Adding a human Fc segment should not affect its immunogenicity, only its half-life in the body.

As stated at page 2 of the specification, IgG has been found to increase the half-lives of several ligand binding proteins (receptors) when used to form recombinant hybrids, including the soluble CD4 molecule, LHR, and the IFN- γ receptor (Mordini J. et al., *Nature*, 337:525-31, 1989; Capon, D.J. and Lasky, L.A., U.S. Patent number 5,116,964; Kurschner, C. et al., *J. Immunol.* 149:4096-4100, 1992). See also U.S. Patent No. 5,428,130. Therefore, in view of the foregoing, there is more than a reasonable expectation that the present invention has the claimed utility.

As for functional variants of the, there are several assay methods available for measuring IFN bioactivity, including the virus cytopathic effect inhibition assay. This assay can be used to evaluate potential variants of IFN without undue experimentation. Moreover, binding affinity for the receptor can also be tested without undue experimentation. These kinds of assays are routine and sequence variation is a commonly used technique.

Conclusion

Applicant asserts that the application is in condition for allowance and requests a timely notice of same.

Respectfully Submitted

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